

*REMARKS/ARGUMENTS**Amendments to the Claims*

Claims 1-4 and 6-29 were pending. Claim 1 is currently amended. Claims 5 and 30 were previously cancelled. Upon entry of this amendment, claims 1-4 and 6-29 will be pending and under active examination in this matter.

Claim 1 has been amended to recite “an administration period of about twelve weeks;” and “wherein the interval between administrations is about one week.” Claim 1 has also been amended to replace the term “wherein the rest period is substantially longer than the interval between administrations” with “wherein the rest period is at least twelve weeks.” Minor changes in punctuation have also been made to claim 1. Support for these amendments can be found throughout the specification as filed, notably at Example 1.

No new matter is added by these amendments.

Amendments to the Specification

The paragraph beginning at page 8, line 26 has been amended to recite the current ATCC Depository address.

No new matter is added by these amendments.

Rejections under 35 U.S.C. § 112, first paragraph

The Office Action states that “the record remains not clear whether the conditions for the deposit of biological materials under 35 U.S.C. § 112, first paragraph ...have been satisfied.” Specifically, the Office Action indicates that the Applicants have not addressed whether all restrictions on the availability of the deposited material will be “irrevocably removed upon the granting of a patent” as per MPEP 2410.01 and 37 C.F.R. 1.808. Applicants respectfully note that a copy of the deposit certificate for ATCC 68720 was included in the submission filed January 5, 2009, which certificate is titled “Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.” The certificate specifies that “The strain will be made available if...a U.S. patent is issued citing the strain.” Applicants respectfully assert that this certificate provides all

information necessary to satisfy the requirements of 37 C.F.R. 1.808. Moreover, as the Office Action acknowledges, ATCC 68720 is referenced in an issued U.S. patent, i.e., U.S. Pat. 6,162,432. Therefore, according to the terms of the deposit as shown on the ATCC certificate, this deposit has already become available for retrieval pursuant to the Budapest Treaty. Accordingly, Applicants respectfully request reconsideration and withdrawal of any remaining rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102 (a), (b), (e)

A. Vaishnaw et al.

Claims 1-4 and 6-29 remain rejected under 35 U.S.C. § 102(a) and (e) as allegedly anticipated by Vaishnaw et al. (US 2004-0170635). The Office Action alleges that “multiple treatments necessarily require an administration and a rest period.” The Office Action further alleges that “the applicant relies upon ‘wherein the rest period is substantially longer than the interval between administrations,’ [but] the claims do not define the ‘rest period’ or ‘substantially longer.’”

Applicants respectfully submit that original claim 23 specified, and in fact presently specifies, that the treatment is administered on a “once-weekly” basis, while the rest period is “at least 12 weeks.” In the interest of advancing prosecution, Applicants have amended claim 1 to specify that “the interval between administrations is about one week,” and to incorporate the term “wherein the rest period is at least twelve weeks.” Vaishnaw does not teach or suggest multiple administration periods interspersed with a rest period of at least twelve weeks as specified in claim 1 or claim 23.

Vaishnaw fails to recite each and every element of the currently rejected claims as required under 35 U.S.C. § 102. Therefore, Applicants respectfully submit that the rejection of claims 1-4 and 6-29 as anticipated by Vaishnaw has been overcome with respect to claim 1 and should be reconsidered and withdrawn with respect to claim 23.

B. Dingivan

Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 102(a), (b) and (e) as allegedly anticipated by Dingivan (US 2003-0044406). As above, the Office Action alleges that “multiple treatments necessarily require an administration and a rest period.”

Like Vaishnaw, Dingivan fails to recite the use of a rest period of at least twelve weeks as identified in the current claims. Therefore, Dingivan also fails to recite each and every element of the currently rejected claims as required under 35 U.S.C. § 102. Accordingly Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-29 as anticipated by Dingivan.

Rejections under 35 U.S.C. § 103

A. Rejection in view of Vaishnaw, Dingivan, and Magilavy

Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Vaishnaw and Dingivan in view of Magilavy et al. (US 2002-0009446). Again, the Office Action relies on the allegation that “multiple treatments necessarily require an administration and a rest period.” As described above, neither Vaishnaw or Dingivan recite a rest period of at least twelve weeks as identified in the current claims. The Office Action does not allege that Magilavy cures this defect, as would be required to make out a prima facie case of obviousness as described in MPEP § 2142. Because the combination of references fails to recite each and every element of the present claims, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-4 and 6-29 as obvious over Vaishnaw or Dingivan in view of Magilavy.

B. Rejection in view of “Known practices in the treatment of psoriasis”

The Office Action further alleges that the present claims are obvious because “[I]t was well known and practice (sic) at the time the invention was made to provide immunosuppressive therapy based on the condition and needs of the patient as evidenced by the teachings of the prior art.” The Office Action appears to allege that the claimed dosing regimen constitutes only optimization of dosing, and that “one of ordinary skill in the art at the time the invention was made would have been motivated to administer immunosuppressant LFA-3 polypeptides over long periods of time, including weeks and years, in order to treat a chronic disease such as psoriasis.”

The present rejection appears to be premised on a reliance on common knowledge in the art. However, in the absence of “instant and unquestionable” documentary evidence, it is not appropriate to rely on such a basis for rejection. MPEP 2144.03. Applicants respectfully

submit that the references cited by the Examiner do not teach or suggest the use of a rest period of at least twelve weeks after a period of weekly dosing. Applicants respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. § 103.

Obviousness-type double patenting

Claims 1-4 and 6-29 are provisionally rejected under the doctrine of obviousness-type double patenting over claims 1-13 of U.S. App. No. 11/398,908 (Magilavy), which was filed April 6, 2006. Neither application has yet been allowed. If the present application (which represents the U.S. national phase of PCT/US05/03907, filed February 7, 2005) should be deemed otherwise allowable prior to the allowance of claims of 11/398,908, Applicants note that the rejection for obviousness-type double patenting should be withdrawn in the present case and addressed in the later-filed application as described in MPEP § 804(I)(B)(1).

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: October 8, 2009